

REMARKS

Claims 1-34 remain pending. Claims 1-4 and 7-34 stand withdrawn from consideration following Applicants' election of Group VIII, claims 5-6, for prosecution on the merits. Applicants respectfully request that any non-elected claims which depend from or otherwise contain all limitations of Group VIII claims be rejoined and allowed upon allowance of the elected Group VIII claims pursuant to M.P.E.P. § 821.04. By the foregoing amendment, the specification has been amended to address an issue raised in the Office Action. Claim 5 has been amended to better define the invention by reciting that the extracellular matrix comprises an inner layer of a cationic or anionic biopolymer and an outer layer of a biocompatible synthetic polyelectrolyte having a charge opposite to that of the biopolymer and which forms a membrane with the biopolymer by complex coacervation. Claim 6 has been amended to recite that the macro-porous exoskeleton comprises alumina or alumina sol at a concentration of about 0.003 to 0.006 M or chitosan at a concentration of about 0.01-0.02%. Support for the amendments is found in the specification, *inter alia*, at page 6, lines 20-25; page 7, lines 27-30; and page 20, lines 1-14. No new matter is added.

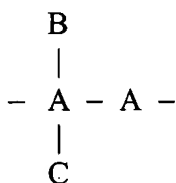
The Office Action objects to the Information Disclosure Statement because the non-patent literature were not listed in the manner required by 37 C.F.R. §§ 1.97 and 1.98. The Examiner is advised that Applicants submitted a Supplemental Information Disclosure Statement on June 16, 2003, which included 43 non-patent references and a PTO-1449 form listing them in compliance with 37 C.F.R. § 1.98. However, an initialed copy of this PTO-1449 form was not included in the Office Action. The Examiner is respectfully requested to initial and return a copy of the PTO-1449 form to the undersigned together with the next Official communication.

The specification stands objected to because page 1 refers to spherical microcapsules as having a “high” surface-to-volume ratio. The Office Action asserts this is incorrect. As the Office Action points out, the volume of a sphere is $\frac{4}{3}\pi r^3$ and the surface area of a sphere is $4\pi r^2$. The surface-to-volume ratio of a sphere therefore is:

$$\frac{4\pi r^2}{\frac{4}{3}\pi r^3} = 3/r$$

A unit sphere ($r = 1$) thus has 3 units of surface area per unit volume. In any event, in an effort to advance prosecution the specification has been amended to delete the term “high” so that the sentence simply reads that the surface-to-volume ratio of a spherical microcapsule facilitates maximal transport of nutrients, gases, or metabolites exchange across the membrane. The amendment is believed to overcome the objection. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

The specification also stands objected to because the notation “mol%” allegedly is unclear. Applicants respectfully submit that this notation is well understood in the chemical arts. Because co-polymers often are made up of monomer units having different molecular weights, the monomer levels frequently are expressed as mol% (or mole %) rather than as a weight percentage. For example, a ter-polymer made up of monomer units “A,” “B,” and “C” and which is represented by the repeating group:



can be described as having 50 mol% A (i.e., two of four monomer units), 25 mol% B (one of four monomer units), and 25 mol% C (one of four monomer units). Applicants respectfully

submit this notation is well understood by persons of ordinary skill and would not be considered unclear. If this objection is maintained, Applicants respectfully request further explanation as well as an indication of alternative notation that would be considered acceptable.

Claim 6 stands rejected under 35 U.S.C. § 112, first paragraph, because the claim is said to be enabled only for concentrations of chitosan of 0.01 to 0.02%. The claim also recites a macro-porous exoskeleton of alumina or alumina sol, which can be used in concentrations of about 0.003 to 0.006 M (see page 20, lines 1-14). In an effort to advance prosecution, claim 6 has been amended to recite that the macro-porous exoskeleton comprises alumina or alumina sol at a concentration of about 0.003 to 0.006 M or chitosan at a concentration of about 0.01-0.02%. The amendments are believed to address and overcome the issue raised in the Office Action. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

Claims 5 and 6 stand rejected under 35 U.S.C. § 112, second paragraph, as failing to particularly point out and distinctly claim the invention. Although Applicants respectfully disagree that original claim 5 is indefinite, in an effort to advance prosecution claim 5 has been amended to define more fully the invention by reciting that the extracellular matrix comprises an inner layer of a cationic or anionic biopolymer and an outer layer of a biocompatible synthetic polyelectrolyte having a charge opposite to that of the biopolymer and which forms a membrane with the biopolymer by complex coacervation.

Section 112, second paragraph, “requires only reasonable precision in delineating the bounds of the claimed invention.” *United States v. Telectronics*, 857 F.2d 778, 786, 8 U.S.P.Q.2d 1217 (Fed. Cir. 1988). In *Modine Mfg. Co. v. United States Int’l Trade Comm’n*, 75 F.3d 1545, 37 U.S.P.Q.2d 1609 (Fed. Cir. 1996), the Federal Circuit explained “a patentee has the right to claim the invention in terms that would be understood by persons of skill in the field

of the invention.” *Ibid*, 75 F.3d at 1557 (emphasis added). Applicants respectfully submit that amended claims 5 and 6 would be understood by persons of skill in the art without recitation of charge densities and molecular weights as suggested in the Office Action. Therefore, claims 5 and 6 are properly definite. Reconsideration and withdrawal of this ground of rejection are respectfully requested.

Claims 5 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Baetge et al. U.S. Patent 5,908,623 (“Baetge”) in light of Koster, “The Extracellular Matrix” webpage (“Koster”). Claims 5 and 6 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Torobin U.S. Patent 5,908,623 (“Torobin”) in light of Koster.

Baetge is cited as describing biocompatible capsules having a core of cells immobilized within an extracellular matrix and an outer jacket surrounding the extracellular matrix. Koster is cited as teaching encapsulated cells can secrete proteins that comprise collagen, fibronectin, and laminin. Torobin is cited as disclosing encapsulating cells within a porous microsphere comprising alumina.

By the foregoing amendment, 5 has been amended to better define the invention by reciting that the microcapsule for culturing anchorage-dependent cells comprises an extracellular matrix having an inner layer of a cationic or anionic biopolymer and an outer layer of a biocompatible synthetic polyelectrolyte having a charge opposite to that of the biopolymer and which forms a membrane with the biopolymer by complex coacervation. The outer shell comprises a macro-porous exoskeleton formed by complex coacervation with this extracellular matrix. None of Baetge, Torobin, and Koster, whether taken alone or in any combination, describes or suggests the particular microcapsule claimed in amended claim 5. Therefore, none

of the cited references anticipates or renders obvious the invention as claimed in amended claims 5 and 6. Reconsideration and withdrawal of the § 102 rejections are respectfully requested.

The Examiner is invited to telephone the undersigned at the number listed below if doing so would be helpful to resolve any outstanding issues.

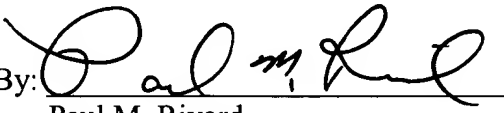
Respectfully submitted,

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